PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	10.03.2005
Applicant's or agent's file reference: RJP/JFB/Y2060	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/04850	10.11.2003	12.11.2002

Applicant: BOOTS HEALTHCARE INTERNATIONAL LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RJP/JFB/Y2060	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/04850	International filing date *(day/month/year)* 10.11.2003	Priority date *(day/month/year)* 12.11.2002
International Patent Classification (IPC) or both national classification and IPC A61J1/00		
Applicant BOOTS HEALTHCARE INTERNATIONAL LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24.05.2004	10.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Cametz, C Telephone No. +31 70 340-3434

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/04850

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-12 filed with telefax on 25.02.2005

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/04850

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-12
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-12
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-12
	No:	Claims	

2. Citations and explanations

   see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/GB 03/04850

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following document:

   D1: WO 02/085429 A (COMAR) 31 October 2002 (2002-10-31)

2. Document D1, which is considered to represent the most relevant state of the art, discloses (see page 6, line 3, to page 7, line 12, and figures; the references in parenthesis applying to this document):

   A liquid dispensing apparatus comprising a bottle (C), a bottle neck liner (30), and a flat-nosed syringe (10) having a plunger (22) and a barrel (12), the barrel terminating at its distal end in a generally flat face (18), the bottle (c) having a bottle neck (32) in which is located the bottle neck liner (30) such that liquid cannot flow between the bottle neck liner and the bottle neck, the bottle neck liner comprising a sleeve comprising an inward step (52, 54) located within the bottle neck (figures. 4B, 5B), an aperture (56, 60) being defined inwardly of the inward step, wherein the sleeve is dimensioned such that when the syringe barrel is inserted into the sleeve the inward step prevents the syringe barrel from protruding past the step and liquid cannot flow between the sleeve and the barrel, but can leave the bottle via the aperture and thence the syringe (figures. 4B, 5B).

   from which the subject matter of D1 differs in that

   the generally flat face of the barrel has
   a diameter corresponding to the diameter of the syringe barrel and being perpendicular to the longitudinal axis of the barrel.

   The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

   The problem to be solved by the present invention may be regarded as improving and simplifying the inter-engagement of the syringe and the liner.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The flat face of the barrel of the syringe does not have any distal projection, so that it is not required, when using the liquid dispensing apparatus, that such a part (i.e. projection) should fit inside an aperture within another part (i.e. neck insertable liner) whether for opening the other part, for secure engagement or for any other reason. A firm inter-engagement of the syringe barrel and the liner is thus obtained by said flat face of the barrel of the syringe.

It is further to be noticed that with the teaching of D1, the skilled person would not be prompted to modify the barrel of the syringe in such a way as disclosed in claim 1, when faced with said objective technical problem.
The skilled person would actually not be incited to "remove" the protrusion of the syringe barrel of D1 in order to improve the inter-engagement of the syringe barrel with the liner.

Hence the subject-matter of claim 1 involves an inventive step and meets the requirements of Article 33(3) PCT.

3. Concerning independent claim 2, document D1, also discloses (see page 6, line 3, to page 7, line 12, and figures; the references in parenthesis applying to this document):

A liquid dispensing apparatus comprising a bottle (C), a bottle neck liner (30), and a flat-nosed syringe (10) having a plunger (22) and a barrel (12), the barrel terminating at its distal end in a generally flat face (18), the bottle (c) having a bottle neck (32) in which is located the bottle neck liner (30) such that liquid cannot flow between the bottle neck liner and the bottle neck, the bottle neck liner comprising a sleeve defining a bore having an inward step (52, 54) located within the bottle neck (figures. 4B, 5B), an aperture (56, 60) being defined inwardly of the inward step, wherein the sleeve is dimensioned such that when the syringe barrel is inserted into the sleeve, the bore sealingly accomodates the distal end region of the syringe barrel, with the distal end region in abutment with the inward step, and wherein liquid cannot flow between the sleeve and the barrel, but can leave the bottle via the aperture and thence the syringe

(figures. 4B, 5B).

from which the subject matter of D1 differs in that

when the syringe barrel is inserted into the sleeve, no part of the distal end of the syringe barrel extends beyond the bore.

The subject-matter of claim 2 is therefore new (Article 33(2) PCT).

The objective technical problem to be solved by the present invention may therefore be regarded, as already mentioned in paragraph 2. above (for claim 1), as improving and simplifying the inter-engagement of the syringe and the liner.

The solution to this problem proposed in claim 2 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the same reasons as mentioned in paragraph 2. above.

Hence the subject-matter of claim 2 involves an inventive step and meets the requirements of Article 33(3) PCT.

4. Claims 3 to 12 are dependent on claim 1 or 2 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

5. The devices and methods described in claims 1 to 12 are industrially applicable and therefore meets the requirements of Article 33(4) PCT.

Certain observations on the international application

1. Claim 12 appears to relate to the same subject-matter as claim 1. The aforementioned claims therefore lack conciseness, contrary to the requirements of Article 6 PCT.

2. According to the requirements of Rule 11.13(m) PCT the same feature shall be denoted by the same reference sign throughout the application. This requirement is not met in view of the use of the reference sign (10) for the inward step on page 16,

line 33, or on page 17, line 11, while the reference sign (18) is used for this same feature on page 14, line 32.
From the figures, it appears that the correct reference sign for said inward step is indeed (18).

3. Independent claims 1, 7 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

4. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

5. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

Claims

1. A liquid dispensing apparatus comprising a bottle, a bottle neck liner and a flat-nosed syringe having a plunger and a barrel, the barrel terminating at its distal end in a generally flat face having a diameter corresponding to the diameter of the syringe barrel and being perpendicular to the longitudinal axis of the barrel, the bottle having a bottle neck in which is located the bottle neck liner such that liquid cannot flow between the bottle neck liner and the bottle neck, the bottle neck liner comprising a sleeve comprising an inward step located within the bottle neck, an aperture being defined inwardly of the inward step, wherein the sleeve is dimensioned such that when the syringe barrel is inserted into the sleeve the inward step prevents the syringe barrel from protruding past the step and liquid cannot flow between the sleeve and the barrel, but can leave the bottle only via the aperture and thence the syringe.

2. A liquid dispensing apparatus comprising a bottle, a bottle neck liner and a flat-nosed syringe having a plunger and a barrel, the bottle having a bottle neck in which is located the bottle neck liner such that liquid cannot flow between the bottle neck liner and the bottle neck, the bottle neck liner comprising a sleeve defining a bore having an inward step located within the bottle neck, an aperture being defined inwardly of the inward step, wherein the sleeve is dimensioned such that when the syringe barrel is inserted into the sleeve, the bore sealingly accommodates the distal end region of the syringe barrel with the distal end region in abutment with the inward step, wherein no part of the distal end extends

beyond the bore, and wherein liquid cannot flow between the sleeve and the barrel, but can leave the bottle only via the aperture and thence the syringe.

3. A liquid dispensing apparatus as claimed in claim 1 or 2, wherein the aperture is pre-formed and permanently open.

4. A liquid dispensing apparatus as claimed in any preceding claim, wherein the bottle neck liner has a cylindrical body to engage sealingly inside the bottle neck, wherein the sleeve is spaced from the body, wherein the body and sleeve are connected together by a web of material only at one end of the body and of the sleeve; and wherein at the other end of the sleeve the inward step is located.

5. A liquid dispensing apparatus as claimed in any preceding claim, wherein the sleeve comprises a resilient material.

6. A liquid dispensing apparatus as claimed in any preceding claim, wherein the inward step is a substantially annular inward step.

7. A liquid dispensing apparatus as claimed in any preceding claim, wherein the inward step is located in the region of one end of the sleeve.

8. A liquid dispensing apparatus as claimed in any preceding claim, wherein the liner comprises an outwardly protruding flange extending around at least a portion of

an end of the liner and abutting the rim of the bottle neck into which the liner is inserted.

9. A liquid dispensing apparatus as claimed in any preceding claim, wherein the bottle contains liquid medicine.

10. A liquid dispensing apparatus as claimed in any preceding claim, wherein the bottle includes a closure member which can be secured over the bottle neck.

11. A method of dispensing liquid from liquid dispensing apparatus as claimed in any preceding claim, the method comprising the steps of:

(a) inserting the barrel of the syringe into the bottle neck of the bottle until the distal end of the barrel abuts the inward step;

(b) positioning the bottle such that liquid within the bottle contacts the aperture;

(c) effecting outward movement of a plunger of the syringe to withdraw liquid from the bottle into the barrel;

(d) positioning the bottle such that liquid within the bottle no longer contacts the aperture;

(e) removing the barrel from the bottle neck; and

(f) effecting inward movement of the syringe plunger to dispense liquid from the syringe barrel.

12. In combination, a flat-nosed syringe and a bottle neck liner, able to produce, with a bottle, a liquid dispensing apparatus as claimed in any of claims 1 to 10.